SARTORIUS

Quality Assurance Certificate

	Sartolab® RF 1000
Order no.	180E05-———E
Use before	03/2030
Pore size	0.22 µm PES
Lot no.	502072276

This document is to verify that the designated product was manufactured by Sartorius according to a Quality Management System that is certified for compliance with current ISO 9001, ISO 13485 and ISO 14001.

Sartorius hereby declares that the designated product was manufactured to meet the current specifications for these products. Sartorius also declares that the designated products have been manufactured from approved materials of construction and comply with design and manufacturing documentation.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released for the following characteristics:
-Membrane integrity test
-Visual attributes
-Packaging

Sterilization
This product has been irradiated and dosimetrically released based upon ANSI/AAMI/ISO 11137 recommended practices.
Sterility Assurance Level: SAL 10^{-6}

Endotoxin Level
An aqueous extraction from the product contains less than 20 EU/product as determined using the Limulus Amebocyte Lysate (LAL) test according to current USP.

Materials Toxicity
Fluid path component materials were tested and determined to be non-cytotoxic in accordance to ISO 10993.

Animal Origin
The product is derived from non-animal and/or non-human source materials or materials that are in accordance with the European Commission's "Note for guidance on minimizing the risk of transmitting animal encephalopathy agents via human and veterinary medicinal products" (EMA/410/01 Rev 3). The information provided is based on documentation that we have received from our suppliers.

Stem-Cell-Certified
The product has been successfully tested for use with human mesenchymal stem cells. A defined, serum-free medium was filtered through Sartolab® vacuum filtration units and used to culture cells over three passages and the results were compared to those obtained with unfiltered medium. No impact on cell growth and critical cell characteristics was observed for the filtered medium.

Membrane Specification
Sartorius certifies that the membrane complies with the following points:

Non-Fiber Releasing Membrane
This product was manufactured using Polyethersulfone microporous membrane which meets the criteria for non-fiber releasing filters as defined in 21 CFR 210.3 (b)(6) of the Food Additive Amendment of the U.S. Federal Food And Drug Act.

Membrane Gravimetric Extractable
The extractable level of the membrane was less than 0.50 weight percent of the membrane.

Membrane Bubble Point Integrity
Samples were tested according to an established procedure to determine the water bubble point of the product. This lot meets the established released criteria of >3.55 bar. Bubble point values are correlated to quantitative bacterial retention requirements as specified by the U.S. Advanced Medical Technology Association (AdvaMed) and/or American Society for Testing Materials (ASTM) guidelines.

Flow Rate
Samples met a flow rate of >44ml/(min cm² bar) deionised water at 20°C.

Bacterial Retention
Samples were quantitatively retentive at $1x10^{7}$ CFU/cm² using Brevundimonas diminuta organisms using HIMA and/or ASTM guidelines.

Membrane Materials Toxicity
All component material have been tested and met the requirements for United States Pharmacopeia (USP) Class VI Biological Test for Plastics, latest Volume.

28.03.2025

This is an electronic document and valid without signature

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